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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MULLEN, KRISTEN DROESCH	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/940,471	RISSMANN ET AL.	
	Examiner	Art Unit	
	Kristen Mullen	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2005 (response)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *195,201-206,209-211 and 213-217* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *195,201,202,204-206 and 209* is/are rejected.

7)☒ Claim(s) *203,210- 211, 213-217* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The indicated allowability of claim s 205, 206 and 209 is withdrawn in view of the newly discovered reference(s) to Cansell (4,825,871), Grevis et al. (4,940,054) and Bardy et al. (6,856,835). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 195 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 195 recites the limitation "the step of sensing an abnormality" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 205, 206 and 209 are rejected under 35 U.S.C. 102(b) as being anticipated by Cansell (4,825,871).

Regarding claim 205, Cansell shows implanting a device having a power source and an energy storage system into a patient; providing a lead system having one or more electrodes (5), the lead system provided such that it is disposed internally to a patient without contacting the

patient's heart (contact with the interior heart walls is prevented via 8, 8' or 100); coupling the power source (13) to the energy storage system; storing energy in the energy storage system; and discharging the energy from the energy storage system to the patient, the step of discharging the energy including using at least one electrode (5) disposed in the lead system; wherein the step of discharging the energy uses a first electrode (5) that is part of the lead system and a second electrode disposed on the device itself (Col 7, lines 13-24; Col 7, lines 46-49; Figs. 1, 1A, 1B, 2A, 2B, 3).

With regard to claim 206, Cansell further shows the step of discharging energy uses only a first electrode (5) that is part of the lead system and an electrode disposed on the device itself (Col. 7, lines 6-13; Col. 7, lines 46-49; Figs. 1, 1A, 1B, 2A, 2B, 3). The use of the word "means" has not been treated by the examiner to invoke a 35 U.S.C. 112, 6th paragraph means plus function limitation because there is sufficient structure recited by the description of an electrode located on the device.

Regarding claim 209, Cansell shows a method comprising: providing a lead assembly including a first electrode (4) implanted in a patient, the lead assembly provided such that it does not contact the patient's heart; providing a device including a battery (13) and a means for storing energy, the device being coupled to the lead assembly; providing a second electrode (10) implanted such that it does not contact the patient's heart; sensing far-field signals using a sensing electrode pair including the first electrode (4) to monitor a portion of the patient's cardiac rhythm; determining whether the patient's cardiac rhythm requires electrical therapy and if so supplying energy from the batter to the energy storage means; and discharging energy stored in the energy storage means to the patient using a stimulus electrode pair (5, 10) including

the second electrode (10); wherein the lead assembly includes a third electrode (5) disposed such that it does not touch the heart; the sensing electrode pair includes the first electrode (4) and the second electrode (10) and the stimulus electrode pair includes the second electrode (10) and the third electrode (5) (Col. 6, line 60-Col. 7, line-29; Col. 7, lines 46-49; Col. 8, lines 45-55; Figs. 1, 1A, 1B, 2A, 2B, 3).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 195 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cansell (4,825,871) as applied above to claim 206, and further in view of Grevis et al. (4,940,054). Cansell is as explained before. Although Cansell fails to specifically teach determining whether the patient has an abnormally slow heart rate, attention is directed to Grevis which shows that it is well known in the field of pacemakers to determine whether the patient has an abnormally slow heartbeat in order to detect and treat bradycardia (Fig. 4). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Cansell to include determining whether the patient has an abnormally slow heartbeat as Grevis teaches since it is well known to do determine whether the patient has an abnormally slow heart rate in the field of pacemakers in order to detect and treat bradycardia.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 201-202 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 6,856,835. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are broader and are met by the narrower patent claims (the patent claims contain all the limitations of the present application claims).

11. Claim 204 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,856,835. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are broader and are met by the narrower patent claims (the patent claims contain all the limitations of the present application claims).

12. Claim 205 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,856,835. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

claims of the present application are broader and are met by the narrower patent claims (the patent claims contain all the limitations of the present application claims).

The description "internally to a patient and not contacting the patient's heart" is broader than "exclusive of the patient's heart". "Internally to a patient and not contacting the patient's heart" can include the interior of the heart as shown by Cansell, and can also include any area exterior of the heart that does not contact the heart as applicants disclose in their specification. Meanwhile, exclusive of the patient's heart can include any area exterior of the heart, but explicitly does not include the interior. In other words, "exclusive of the patient's heart" is a narrower definition because fewer locations within the patient will meet this definition that the definition "not contacting the patient's heart"

Allowable Subject Matter

13. Claims 203, 210-211, 213-217 are allowed.

14. Claims 201-202 and 204 would be allowable if rewritten or amended to overcome the Double Patenting rejection set forth in this Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kristen Mullen/

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3762

kdm